

REMARKS/ARGUMENTS

Claims 1-17 and 29-32 are pending in the captioned application. Applicants have amended claim 1 and cancelled claims 31-32. Applicants respectfully request reconsideration in view of the amendments and the following arguments.

The 35 U.S.C. §112 rejection of claims 1-17, 29-30 and 32 is moot in view of the amendment. In particular, claim 1 has been amended to require the presence of 4-8% nonionic polyether. Support can be found in Figure 8. As indicated by the Examiner, this range is clearly supported by the specification and thus is enabled.

Claims 1-3, 5-17 and 29-32 stand rejected under 35 U.S.C. §103(a) as being obvious over Shadle et al. in view of Gagnon et al. Applicants respectfully disagree.

In response, Applicants first submit that there appear to be an error when the Examiner states that these claims “are rejected under 35 U.S.C. 102(b) as being anticipated...” (page 4). Applicants note that the rejection is made under the heading of “Claim Rejections – 35 § 103”. Further, the Examiner states “Shadle et al. do not disclose using non-ionic polyethylene glycol for isolation and purification of the target proteins.”

With regard to the rejection of the claims over Shadle in view of Gagnon, Applicants first submit that neither Shadle nor Gagnon mention the 1.5 times capacity increase feature of claim 1. The Examiner states that in Gagnon “The recovery is more than 1.5 times (see Figure 1)”. (Page 5, lines 1-2). The Examiner seems to imply that the capacity is increased >1.5 times. Applicants submit that such is not the case.

Figure 1 of Gagnon shows that the retention of the protein R-phycoerythrin (RPE) is increased three times upon addition of 10% PEG-6000. Retention is measured by injecting the protein on the column and eluting in a 0-1 M NaCl gradient and noting the elution position of the protein in the gradient. (Page 2, 1st paragraph). This elution position (NaCl concentration at the peak center) is the Y axis of Figures 1-5 and indicates how much salt is needed to break the bonds between the protein and the charged ligands. Gagnon does not discuss anything about the binding capacity, which is the amount of protein that binds to the resin. Applicants submit that it is indeed possible to have a high retention at the same time as a low capacity (only a small amount of protein binds but it binds very strongly).

Applicants further submit that the references should not be combined. Gagnon describes addition of PEG in anion and cation exchange chromatography to improve the selectivity between proteins, particularly in cases where a small protein elutes before a larger one. Gagnon does not discuss capacity at all and does not give any suggestions of using a multi-step chromatography process. Gagnon also downplays the practical usability of PEG addition (pages 3 and 4) and indicates that it can be detrimental in many cases, causing more peak broadening than selectivity improvement and in cases where a small protein elutes after a larger one it will even have negative effects on the selectivity. Applicants submit that peak broadening is normally associated with decreased dynamic capacity. Thus, the skilled person in the art of chromatography would interpret the data in Gagnon Fig 6 to mean that PEG

addition decreases dynamic capacity. The skilled person would be discouraged from combining Gagnon with Shadle.

Thus, even if the references are combined, claims 1-3, 5-17 and 29-30 are not rendered obvious by the combination.

Claim 4 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Shadle in view of Gagnon, further in view of Bandler. Applicants respectfully disagree. Applicants submit that as discussed above, the amended claim 1 is patentable. Therefore, the dependent claim 4 is also patentable.

Applicants respectfully assert that the claims are in allowable form and earnestly solicit the allowance of the claims 1-17 and 29-30.

Early and favorable consideration is respectfully requested.

Respectfully submitted,

GE Healthcare Bio-Sciences Corp.

By: /Yonggang Ji/
Yonggang Ji
Reg. No.: 53,073
Agent for Applicants

GE Healthcare Bio-Sciences Corp.
800 Centennial Avenue
P. O. Box 1327
Piscataway, New Jersey 08855-1327

Tel: (732) 980-2875
Fax: (732) 457-8463

I hereby certify that this correspondence is being uploaded to the United States Patent and Trademark Office using the Electronic Filing System on March 16, 2010.

Signature: /Melissa Leck/

Name: Melissa Leck

Appl. No. 10/594,187
Amendment dated March 16, 2010
Reply to Office action of December 16, 2009